THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte PANOLIL C. RAVEENDRANATH
and JOHN A. WICHTOWSKI

_____

Appeal No. 95-2993
Application 08/019,387[1]

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ON BRIEF

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Before WILLIAM F. SMITH, METZ and ELLIS, **Administrative Patent Judges**.

ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2 through 12 and 14, all the claims remaining in the application. Claims 1 and

[1]Application for patent filed February 18, 1993. According to the appellants, this application is a continuation-in-part of Application 07/841,694, filed February 26, 1992, now U.S. Patent 5,210,081.

13 have been canceled. Claims 14 and 9 are illustrative of the subject matter on appeal and read as follows:

9. A method for the treatment of atherosclerosis which comprises administering to a patient in need of anti-atherosclerotic treatment, an effective amount of 8,9-dehydroestrone or a salt of 8,9-dehydroestrone sulfate ester.

14. A pharmaceutically acceptable alkaline earth meal, ammonium or amine salt of 8,9-dehydroestrone-3-sulfate ester free from other estrogenic steroids, wherein the amine of said salt is selected from the group consisting of an alkylamine of 1 to 6 carbons atoms and a dialkylamine in which each alkyl group has, independently, 1 to 6 carbon atoms.

Claims 2 through 12 and 14 stand rejected under 35 U.S.C. § 112, first paragraph, as "failing to adequately teach how to use the invention." Answer, p. 3.

We ***reverse***.

In reviewing the rejection, we find that the examiner is primarily concerned with whether the claimed compounds "are useful for the treatment of estrogen related disorders or atherosclerosis" and, thus, whether the specification would have enabled one skilled in the art to use the claimed compounds for said treatments. Answer, pp. 4 and 6.

The appellants point out, and the examiner does not contest, that the claimed compounds are estrogenic steroids. It is the appellants' position that since medical practitioners have been using estrogens for many years, once they are informed that a steroid is estrogenic, "they know how to use them without detailed instruction." Brief, p. 2. We agree.

A patent "specification need not disclose what is well known in the art" in order to satisfy the enablement requirement of 35 U.S.C § 112. ***Genentech Inc. v. Novo Nordisk A/S*****,** 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997); ***Hybritech Inc. v. Monoclonal Antibodies, Inc.***, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). To that end, we direct attention to the disclosure in the specification that the claimed invention is directed to "a group of pharmaceutically acceptable salts of 8,9 dehydroestrone sulfate ester." Specification, p.1, lines 32- p. 2, line 6. The specification further discloses that

> 8,9-Dehydroestrone is a known compound useful as an intermediate in the synthetic production of estrone by isomerization to 9,11 unsaturation (U.S. 3,394,153) and as an intermediate in the production of 3-cyclopentyloxy-17-ethynyl derivatives (Example XXVIII, U.S. 3,649,621). In addition, 8,9-dehydroestrone is known to possess estrogenic activity and to lower blood lipid levels (Examples 11 and 12; US 3,391,169) [Specification, p. 1, lines 23-28].

In addition, we note that the patented parent (U.S. 5,210,081) of the present application discloses that another member of the group of salts of 8, 9 dehydroestrone sulfate esters, an alkali metal salt of 8,9 dehydroestrone-3-sulfate ester, possesses estrogenic activity and is useful for the treatment of atherosclerosis.[2] U.S. 5,210,081, col. 4, line 65- col. 5, line 1. Thus, we find that the record establishes that the use of estrogenic compounds to lower blood lipid levels and to treat atherosclerosis was well

[2] We point out that the experiments disclosed in the parent application to support the usefulness of the compounds claimed therein are remarkably similar to the experiments disclosed in the present application. U.S. 5,210,081, Example 7.

known in the art. Accordingly, we conclude that the specification disclosure as to the estrogenic activity of the claimed compounds would have enabled those skilled in the art to use the claimed compounds for the treatment of estrogen-related disorders and atherosclerosis.

In view of the foregoing, the rejection is reversed.

Other Issues

We note that claims 9 and 11 are directed to the treatment of atherosclerosis using 8,9 dehydroestrone. To that end, we direct attention to our discussion, above, that the specification refers to a U.S. patent for its disclosure that 8,9 dehydroestrone is known to possess estrogenic activity and to lower blood lipid levels. Specification, p. 1, lines 23-28. In their brief, the appellants state that 8,9 dehydroestrone (i) is known to possess estrogenic activity (is an active steroid) and that persons skilled in the art know how to use such compounds without detailed instruction (Brief, para. bridging pp. 2-3), and (ii) is a useful antilipidemic agent as shown by U.S. 3,391,169 (Brief, p. 4, last para.).

In view of these admissions, upon return of this application to the corps, the examiner and the appellants should consider whether it was known in the art to use 8,9 dehydroestrone in the methods described in claims 9 and 11. Alternatively, the examiner might wish to consider whether the teachings of the referenced U.S. patent

would have suggested the presently-claimed methods to one of ordinary skill in the art.

In addition, we note that the file wrapper of the instant application indicates that the examiner did not search any of the available electronic databases. Thus, upon return of the application, the examiner should also consider whether he has located and reviewed all the relevant prior art.

REVERSED

William F. Smith	)
Administrative Patent Judge	)
	) BOARD OF PATENT
	)
	) APPEALS AND
Joan Ellis	)
Administrative Patent Judge	) INTERFERENCES

JE/dm

Metz, Administrative Patent Judge, Concurring-in-part, dissenting-in-part.

I agree with the decision of the majority reversing the rejection of claims 2 through 12 and 14 under 35 U.S.C. § 112, first paragraph. However, I would not leave the important questions denominated by the majority as "Other Issues" in legal and procedural limbo but would exercise the Board's authority under 37 C.F.R. § 1.196(b). I would make rejections of claims 9 through 12 as unpatentable under 35 U.S.C. § 103 as the subject claimed therein would have at least been *prima facie* obvious from the admitted disclosure in Hughes et al. of 8,9-dehydroesterone as a known steroid possessing estrogenic activity. Accordingly, I dissent-in-part from the majority's opinion. Further, pursuant to 37 C.F.R. § 1.196(b), I would also enter a rejection of claims 9 and 11 as being unpatentable on the grounds of obviousness-type double patenting over the claims of U.S. Patent Number 5,210,081.

Claims 9 through 12 comprise a method of treatment comprising administering to a patient in need of anti-atherosclerotic treatment an effective amount of either 8,9-dehydroestrone or a salt of 8,9-dehydroestrone sulfate ester. Thus, claims 9 through 12 embrace administering to a patient in need of treatment 8,9-dehydroestrone. As noted

by the majority, appellants disclose in their specification at page 1, lines 26 through 28 that 8,9-dehydroestrone:

> is known to possess estrogenic activity and to lower blood lipid levels (Examples 11 and 12; US 3,391,169).

In my view, this disclosure constitutes an admission by appellants that one of the compounds of their claimed method was known at the time appellants' invention was made to possess utility which *prima facie* would have indicated said compound would be expected to be useful in treating atherosclerosis. That is, 8,9-dehydroestrone is known to possess estrogenic activity and the ability to lower blood lipid levels. Accordingly, I find claims 9 through 12 would have at least been *prima facie* obvious from Hughes et al.

By making a rejection under 37 C.F.R. § 1.196(b), appellants and the examiner would be required to proceed under well-recognized procedures set forth in the rule after appellants elect either further prosecution before the examiner or rehearing before the Board. The majority, by merely denominating issues which go the patentability of the claims before us as "other issues" for the examiner and appellants to deal with as they choose, are leaving the determination of the patentability of appellants' claims to another forum. We should exercise our discretion, provide appellants with the safeguards of the rule and make the rejection under 37 C.F.R. § 1.196(b).

Based on the same rationale as expressed above for exercising our authority under 37 C.F.R § 1.196(b), I would also reject appellants' claims 9 and 11 over the claims of appellants' earlier patent, U.S. Patent Number 5,210,081 claims, on the grounds of

obviousness-type double patenting. The claims of appellants' earlier patent are directed to alkali metal salts of 8,9-dehydroestrone-3-sulfate ester. The alkali metal salts of appellants' earlier patent are "estrogens useful in replacement therapy in estrogen therapy in estrogen deficiency. Further, they are useful in suppression of lactation, prophylaxis and treatment of mumps orchitis, treatment of atherosclerosis and senile osteoporosis." (column 4, line 65 through column 5, line 2). There are no method claims in appellants' earlier patent.

Nevertheless, because a compound and its properties are inseparable and because claims 9 and 11 in this appeal include the alkali metal salts of 8,9-dehydroestrone-3-sulfate ester, based on the disclosed utilities for the alkali metal salts of 8,9-dehydroestrone-3-sulfate ester in appellants' earlier patent, the methods now claimed by appellants in this application would have been obvious from the compounds' inherent properties. To now permit appellants to extend their right to exclude others by providing appellants with a new patent term for subject matter they could have presented in their earlier application would be improper. In re Berg, 140 F.3d 1428, 1431, 1432, 1435, 46 USPQ2d 1226, 1229, 1232 (Fed. Cir. 1998). Additionally, our reviewing court has sanctioned the practice of basing an obviousness-type double

patenting rejection on a patent directed to a different statutory class of invention than is

now being claimed. In re Lonardo, 119 F.3d 960, 968, 43 USPQ2d 1262, 1268 (Fed. Cir. 1997).

	) BOARD OF PATENT
Andrew H. Metz	)
Administrative Patent Judge	) APPEALS AND
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